Improved outcomes are associated with multilevel endovascular intervention involving the tibial vessels compared with isolated tibial intervention

Mikel Sadek, MD,[a] Sharif H. Ellozy, MD,[b] Irene C. Turnbull, MD,[b] Robert A. Lookstein, MD,[b] Michael L. Marin, MD,[b] and **Peter L. Faries, MD,[b]** *New York, NY*

Objective: **Endovascular intervention is increasingly accepted as an alternative to surgery for the treatment of tibial vessel disease. Tibial vessel disease can occur in isolation or in conjunction with disease that involves the proximal lower extremity vasculature (multilevel disease). This study evaluated the overall efficacy of endovascular intervention for tibial vessel disease and whether the requirement for single-level compared with multilevel intervention affected outcomes.**

Methods: **This study evaluated a consecutive unselected group of patients who underwent an infrapopliteal intervention from November 2002 to February 2008. The primary end points evaluated were technical success, limb salvage, primary patency, and secondary patency. The secondary end points evaluated were 30-day access site (ie, hematoma, pseudoaneurysm, and wound infection), intervention site (ie, thrombosis), and systemic (ie, acute renal failure, myocardial infarction, and mortality) complications. Patency and limb salvage were evaluated using Kaplan-Meier life-table analyses and compared using Cox regression analysis. $P < .05$ was considered statistically significant.**

Results: **The study comprised 85 patients, 89 limbs, and 114 procedures. Age was 72.4 ± 13.1 years, 67% were men, and follow-up was 245.8 ± 290.8 days. The technical success rate for all procedures was 91%. Limb salvage rates for patients with critical limb ischemia at 6, 12 and 18 months were 85% ± 0%, 81% ± 0%, and 69% ± 0%, respectively. For the complete patient cohort, primary patency rates at 6, 12 and 18 months were 68% ± 6%, 50% ± 8%, and 37% ± 9%, respectively, and secondary patency rates were 81% ± 5%, 71% ± 7%, and 63% ± 8%. Multilevel intervention was associated with significantly improved secondary patency compared with single-level intervention ($P = .045$).**

Conclusions: **Patency and limb salvage rates for endovascular treatment of tibial vessel disease in this study are comparable with prior reports and with historical surgical controls. Patients who undergo multilevel intervention involving the tibial vessels exhibit improved secondary patency compared with those who undergo intervention for lesions isolated to the tibial vessels. This may reflect increased distal disease burden for patients who undergo isolated tibial intervention. The study data suggest that the presence of multilevel disease should not preclude an attempt at percutaneous revascularization. Further study is required before formulating definitive recommendations for the endovascular treatment of tibial vessel disease. (J Vasc Surg 2009;49:638-44.)**

Lower extremity peripheral arterial disease (PAD) is a major cause of morbidity and mortality that affects approximately 27 million people in North America and Europe.[1] Symptoms range from claudication to limb-threatening critical limb ischemia (CLI), which is exemplified by rest pain, ulceration, and gangrene. Typically, exercise therapy and medical optimization are used to treat intermittent claudication, and surgery is reserved for claudication that is refractory to conservative management or for CLI.

Surgical approaches are associated with an increased risk for systemic and local complications due to the multiple comorbidities that characterize the typical patient with lower extremity PAD.[2] As a consequence, percutaneous endovascular therapy is increasingly being accepted as an alternative to surgery for the treatment of PAD. The most recent TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC-II) guidelines delineate specifically those lesions in the aortoiliac and femoropopliteal regions that are suitable for treatment using endovascular therapy compared with surgery.[2] The TASC-II recommendations are less well defined for infrapopliteal disease due to limited available data on safety and efficacy.

Infrapopliteal PAD may occur in isolation or simultaneously with proximal level disease. Patients with multilevel disease are frequently older, have multiple comorbidities, exhibit increased vascular compromise, and fair worse after endovascular intervention than patients with isolated disease of the aortoiliac or femoropopliteal vasculature.[3-5] A comparison has not yet been made between single-level intervention of the infrapopliteal vasculature and multilevel intervention involving the infrapopliteal vasculature. This study sought to assess the overall efficacy of endovascular intervention in a cohort of patients with disease of the infrapopliteal vasculature. In addition, this study evaluated whether the requirement for single-level compared with

From the Department of Surgery, New York University School of Medicine,[a] and Department of Surgery, Division of Vascular Surgery, Mount Sinai School of Medicine.[b]

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Reprint requests: Peter L. Faries, MD, FACS, Chief, Division of Vascular Surgery, Mount Sinai School of Medicine, 5 E 98th, Box 1273, New York, NY 10029-6574 (e-mail: peter.faries@mssm.edu).

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multilevel intervention affected the outcomes of patients treated for disease of the infrapopliteal vasculature.

METHODS

This study was a retrospective review of a prospectively maintained database of a consecutive unselected group of patients who underwent infrapopliteal endovascular treatment for lower extremity PAD from November 2002 to February 2008. All patients who had undergone a tibial intervention were included in the study. All procedures were performed by faculty of the Divisions of Vascular Surgery from the Mount Sinai School of Medicine and from the Weill Medical College of Cornell University. The Ethics Committee and Internal Review Board approved the study protocol.

Patients. A total of 114 infrapopliteal endovascular procedures were performed on 89 limbs from 85 patients, with an average follow-up of 245.8 ± 290.8 days. All patients who underwent infrapopliteal endovascular intervention during the study period were included in the analysis.

Preprocedural patency was determined using a combination of history and physical examination and duplex ultrasound imaging. Angiography was reserved for patients who were considered for reintervention. Preprocedural characteristics included age (72.4 ± 13.1 years; range, 43-92 years), gender (67% men), claudication (23%), CLI (77%), rest pain (23%), tissue loss (54%), stable angina (22%), unstable angina (4%), congestive heart failure (15%), history of coronary artery bypass graft (20%), coronary artery disease (48%), history of myocardial infarction (21%), cancer (13%), chronic obstructive pulmonary disease (COPD; 12%), chronic renal insufficiency (17%), creatinine level >1.2 mg/dL (37%), diabetes mellitus (58%), end-stage renal disease (ESRD; 15%), hyperlipidemia (54%), hypertension (84%), prior ipsilateral lower extremity bypass (15%), and tobacco use (51%).

The patients who required reintervention after lower extremity bypass had failed bypass grafts. Percutaneous intervention at anastomotic sites was not evaluated in this study. In addition, no patients had undergone prior endovascular interventions.

Patients were stratified according to whether they had undergone single-level intervention isolated to the tibial arteries or multilevel intervention, which was defined as intervention of the tibial arteries in addition to simultaneous intervention of the proximal femoropopliteal vasculature. Staged interventions were not evaluated as multilevel interventions. When stratifying patients to single-level vs multilevel intervention, the preprocedural characteristics that differed significantly were stable angina (single-level, 43% vs multilevel, 18%; $P = .018$), creatinine >1.2 mg/dL (single-level, 41% vs multilevel, 10%; $P = .002$), ESRD (single-level, 29% vs multilevel, 8%, $P = .022$), and COPD (single-level, 0% vs multilevel, 21%; $P = .007$; Table I).

Procedures. Endovascular procedures were performed in an operating room angiography suite or in an interventional radiology suite using a fixed imaging system. All procedures were performed under local anesthesia using intravenous sedation. A contralateral femoral up-and-over approach was used in 63% of interventions, and an ipsilateral antegrade approach was used in 37%.

Table I. Preprocedural characteristics for single-level versus multilevel intervention

Characteristic	*Single-level (n = 29)*	*Multilevel (n = 60)*	P[a]
Demographics			
Age, mean ± SD, y	70 ± 13.8	74 ± 12.6	NS
Gender (male), %	59	67	NS
Preprocedural symptoms, %			
Claudication	17	25	NS
Critical limb ischemia	83	75	NS
Rest pain	21	18	NS
Tissue loss	62	57	NS
Preprocedural cardiac history, %			
Angina, stable	43	18	.018
Angina, unstable	7	2	NS
Congestive heart failure	29	13	NS
Coronary artery bypass graft	15	25	NS
Coronary artery disease	50	47	NS
Myocardial infarction	11	23	NS
Preprocedural noncardiac history, %			
Cancer	14	14	NS
COPD	0	21	.007
Creatinine >1.2 mg/dL	41	10	.002
Diabetes	71	61	NS
End-stage renal disease	29	8	.022
Hyperlipidemia	68	47	NS
Hypertension	86	88	NS
Lower limb bypass (ipsilateral)	14	12	NS
Tobacco use	43	65	NS

COPD, Chronic obstructive pulmonary disease.
[a]Significance set at $P < .05$.

The breakdown of the percutaneous interventions performed was as follows: angioplasty alone, 62%; angioplasty with stent placement, 28%; laser atherectomy (Spectranetics Corp, Colorado Springs, Colo), 3%; cryoplasty (Boston Scientific, Natick, Mass), 3%; excisional atherectomy (Fox Hollow Technologies, Redwood City, Calif), 2%; Angiojet (Possis Medical Inc, Minneapolis, Minn), 1%; drug-eluting stent (Cordis, Warren, NJ), 1%; and thrombolysis, 1%. Stenting was used selectively in patients who exhibited a flow-limiting dissection or residual stenosis. In the current study, all patients who received stenting, received stenting of the tibial arteries. Angiojet and thrombolysis were used in a case where thrombus was thought to complicate the stenosis.

Intraprocedural and periprocedural anticoagulation and antiplatelet therapy with aspirin or clopidogrel, or both, were administered at the discretion of the investigator. In general, patients were systemically anticoagulated intraprocedurally using intravenous unfractionated heparin with a goal of an activated clotting time of >250 seconds. Aspirin (Bayer, Leverkusen, Germany) was administered to

all patients postprocedurally unless contraindicated. For patients undergoing stent placement or atherectomy, clopidogrel (Sanofi-Aventis, Bridgewater, NJ) was administered postprocedurally for a minimum of 30 days.

Follow-up. Postprocedural follow-up regimens were left to the discretion of the investigator. In general, patients were monitored with regular physical examinations, ankle-brachial indices/pulse-volume recordings, and arterial duplex examinations. Additional imaging was obtained as clinically indicated.

End points. Primary end points included technical success, limb salvage, and primary and secondary patency. Technical success was defined as antegrade flow through the treated lesion with a residual stenosis of <30% at the end of the procedure. Limb salvage was defined as resolution of rest pain or freedom from amputation, including and proximal to the transmetatarsal level, and this was only evaluated in patients who presented with CLI. Patients who presented with claudication were excluded from the analysis of limb salvage.

Primary patency was the duration of follow-up during which there was an absence of occlusion or restenosis within the treated segment. Secondary patency was the duration of follow-up before the requirement for a salvage intervention for an occlusive lesion. In patients with multilevel interventions, loss of patency at a single treated level was considered a treatment failure for the entire limb. Secondary end points included 30-day access site (ie, hematoma, pseudoaneurysm and wound infection), intervention site (i.e. thrombosis), and systemic complications (ie, acute renal failure, myocardial infarction, and death). The postprocedural length of stay was also evaluated.

Statistical analysis. All statistical analyses were performed using SPSS 16.0 software (SPSS Inc, Chicago, Ill). Preprocedural characteristics were reported as a mean ± standard deviation or as a percentage of the total number of interventions, where appropriate. Discrete variables were analyzed using the two-tailed Fisher exact test, and continuous variables were analyzed using the two-tailed unpaired *t* test. Limb salvage and rates of primary and secondary patency were evaluated using the Kaplan-Meier life-table analysis and compared using a Cox regression analysis. $P < .05$ was considered statistically significant.

RESULTS

Procedural characteristics. The technical success rate for all procedures was 91%. The results for the 30-day secondary end points were access site complications, including hematoma (4%), pseudoaneurysm (2%), and wound infection (3%); intervention site complications, consisting of thrombosis (2%); and systemic complications, including myocardial infarction (1%) and mortality (1%). The average postprocedural length of stay was 6.2 ± 9.9 days (range, 1-57 days). Complication rates were low overall and did not differ significantly between patients who underwent single-level compared with multilevel intervention. In addition, complication rates did not differ significantly between patients who were treated using a contralateral compared with an antegrade approach.

Table II. Log rank analysis of limb salvage rates for patients with critical limb ischemia and of patency rates for the complete patient cohort

Characteristic	*Single-level (n = 29) Mean ± SD, %*	*Multilevel (n = 60) Mean ± SD, %*	P[a]
Limb salvage			
6 months	83 ± 7	88 ± 5	NS
12 months	75 ± 10	84 ± 6	NS
18 months	67 ± 12	63 ± 19	NS
Primary patency			
6 months	62 ± 10	71 ± 8	NS
12 months	34 ± 12	58 ± 9	NS
18 months	27 ± 11	48 ± 12	NS
Secondary patency			
6 months	65 ± 10	89 ± 5	.045
12 months	52 ± 12	85 ± 6	.045
18 months	46 ± 12	57 ± 18	.045

[a]Significance set at $P < .05$.

Limb salvage rates for patients who presented with CLI were 85% ± 0% at 6 months, 81% ± 0% at 12 months, and 69% ± 0% at 18 months. Primary patency rates for the complete patient cohort were 68% ± 6% at 6 months, 50% ± 8% at 12 months, and 37% ± 9% at 18 months, Secondary patency was 81% ± 5% at 6 months, 71% ± 7% at 12 months, and 63% ± 8% at 18 months.

All patients who presented with claudication did not progress to critical limb ischemia. As a corollary, no claudicant patients required reintervention. A total of 26 initially treated tibial vessels required reintervention to attain secondary patency. The lesion location distribution was anterior tibial in 38%, peroneal in 31%, tibioperoneal trunk in 23%, and posterior tibial in 8%.

Log-rank analysis demonstrated that single-level and multilevel intervention differed significantly with regards to secondary patency (Table II). Multilevel intervention was associated with significantly improved secondary patency rates compared with single-level intervention ($P = .045$; Figs 1-3). Stable angina, creatinine >1.2 mg/dL, and ESRD were more prevalent in patients who underwent single-level intervention. COPD was more prevalent in patients who underwent multilevel intervention (Table I). The comorbidities of stable angina, elevated creatinine, ESRD, and COPD did not correlate significantly with primary or secondary patency or limb salvage in patients treated using single-level vs multilevel interventions.

DISCUSSION

Patients with lower extremity PAD exhibit significant variability in clinical presentation and in the localization of disease within the lower extremity vasculature. Patients may present with symptoms that range from intermittent claudication to rest pain or to tissue loss. The pattern of localization of vascular disease that results in clinically significant sequelae ranges from a lesion that is isolated to a

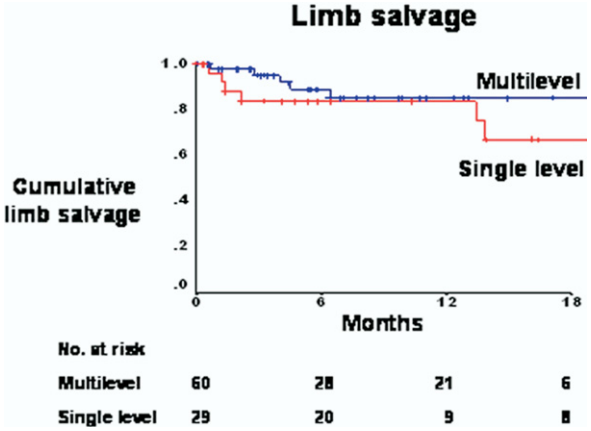

Fig 1. Limb salvage rates for patients with critical limb ischemia stratified by single-level vs multilevel intervention.

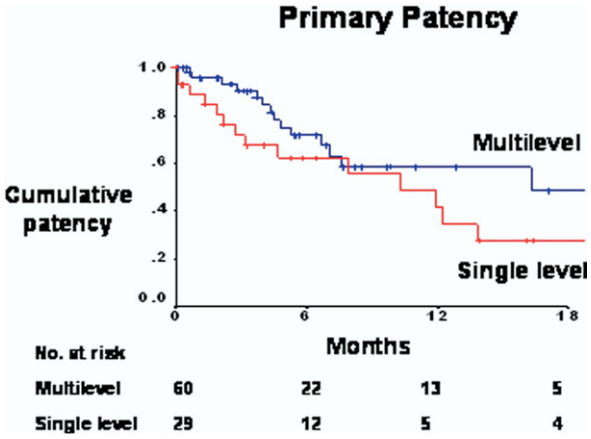

Fig 2. Primary patency rates for the complete patient cohort stratified by single-level versus multilevel intervention.

single level in the lower extremity vasculature to lesions that present simultaneously at multiple levels. This study evaluated patients who were treated for disease of the infrapopliteal vasculature, which presented as single-level or multilevel disease.

The risk factors that characterize disease of the infrapopliteal vasculature are similar to those that characterize aortoiliac and femoropopliteal disease: advanced age, smoking, diabetes, hypertension, hyperlipidemia, male gender, prior myocardial infarction, and heart failure.[3,6-8] In particular, diabetes affects 63% to 91% of patients undergoing treatment for infrapopliteal PAD.[9]

Revascularization therapy may consist of endovascular therapy or surgical bypass. In general, patients treated for severe infrapopliteal disease exhibit diminished long-term patency for both surgical bypass and endovascular intervention with patients with disease isolated to the more proximal vasculature.[10,11]

Initially, the endovascular treatment of lower extremity PAD involving the infrapopliteal vasculature was limited

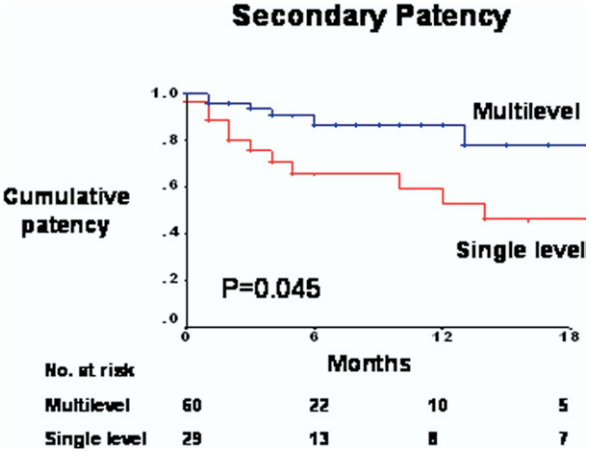

Fig 3. Secondary patency rates for the complete patient cohort stratified by single-level vs multilevel intervention. Cox regression analysis demonstrated that multilevel intervention was associated with significantly improved secondary patency rates as compared to single-level intervention ($P = .045$; Table II).

before the development of low-profile balloon catheters and steerable guidewires.[12] As a consequence, early experience with the endovascular treatment of infrapopliteal PAD generated poor immediate and long-term outcomes.[13,14] Some of the potential factors that contributed to the initially poor outcomes included long-segment disease, occluded lesions, compromise to outflow vessels, and the potential compromise to future surgical bypass. Advances in endovascular technique and the use of adjunctive modalities have generated improved outcomes for the endovascular management of lower extremity PAD.[15]

The updated TASC-II guidelines state that for the endovascular treatment of infrapopliteal disease, angioplasty may be indicated for limb salvage but should not be used for the treatment of intermittent claudication.[2] The guidelines further state that there is evidence for the treatment of short tibial artery stenoses if the patient is simultaneously undergoing treatment for femoropopliteal disease. In addition, the treatment of tibial artery occlusions should be reserved for cases where in-line flow to the pedal vasculature can be re-established. In the current study, the treatment of patients who presented with claudication was performed infrequently and only if the disease limited perfusion to the leg.

Currently, no level I data evaluate the treatment of infrapopliteal PAD using endovascular therapy. In general, technical success and clinical success rates approach 90% and 70%, respectively.[2] With regards to angioplasty as the treatment modality, a retrospective review of 67 patients with CLI treated using infrapopliteal angioplasty demonstrated a technical success rate of 86% and a 3-year limb salvage rate of 94%.[16] Another review of 46 patients with CLI treated using infrapopliteal angioplasty demonstrated a technical success rate of 80% and a 2-year limb salvage rate of 87%.[17] A review that evaluated the treatment of CLI

using subintimal angioplasty for occluded tibial vessels demonstrated 1-year primary, secondary, and clinical patency rates of 46%, 55%, and 63%, respectively. Limb salvage rates at 1 and 2 years were 87%.[18]

Bosiers et al[19] performed one of the largest retrospective reviews in patients treated for CLI using infrapopliteal endovascular therapy. A total of 681 below knee interventions were performed in 443 patients with CLI. Patients were treated using angioplasty alone, angioplasty with stenting, or laser atherectomy (Spectranetics Corp, Colorado Springs, Colo). Primary patency rates were, respectively, 85.2% and 74.2% at 6 months and 1 year, and limb salvage rates were 97.0% and 96.6%. Subset analyses comparing the different treatment modalities did not demonstrate any statistically significant differences. The results of the retrospective reviews evaluating infrapopliteal endovascular therapy compare favorably with historical surgical controls. Level I evidence is still required to determine definitive management.

Disease of the infrapopliteal vasculature is a likely indicator of significant atherosclerotic burden. As a consequence, infrapopliteal PAD is frequently accompanied by disease of the proximal lower extremity vasculature. The endovascular treatment of multilevel disease is thought to result in worse outcomes compared with the treatment of single-level disease of the femoropopliteal or aortoiliac vasculature, because each lesion has its own failure rate that results in an additive effect.[2] In addition, patients with multilevel disease are frequently older, have more comorbidities, and have lower baseline ankle-brachial indices than patients with single-level disease.[3-5] A comparison has not yet been made between single-level interventions of the infrapopliteal vasculature and multilevel interventions involving the infrapopliteal vasculature.

This study evaluated patients with lower extremity PAD who underwent endovascular treatment of the infrapopliteal vasculature in addition to treatment of the proximal vasculature, as indicated. The technical success rate of the entire patient cohort (91%) was comparable with other retrospective reviews, and the primary patency and secondary patency and limb salvage rates were also comparable with other reports. Log-rank analysis demonstrated that multilevel intervention was associated with significantly improved secondary patency compared with single-level intervention ($P = .045$). Stable angina, creatinine >1.2 mg/dL, and ESRD were more prevalent in patients who underwent single-level intervention, and COPD was more prevalent in patients who underwent multilevel intervention.

One explanation for the study results is that patients with single-level disease may exhibit locally increased atherosclerotic burden compared with patients with multilevel disease. This may have resulted in the increased frequency of secondary interventions that were performed in patients with single-level infrapopliteal disease. Diabetes was not found to be more prevalent in patients with single-level disease, and this is a significant risk factor for PAD that involves the infrapopliteal vasculature.[9]

A limitation of this study is that consensus guidelines currently do not exist for classifying tibial lesions. Therefore, preoperative lesion characteristics could not be compared between patients treated using single-level compared with multilevel intervention.

In addition, preprocedural patient characteristics, comorbidities, and indications for surgery were not equivalent between the two patient cohorts due to the absence of randomization. Specifically, there was a nonsignificant trend towards an increased incidence of CLI in patients who underwent single-level infrapopliteal intervention. Nevertheless, no significant differences were noted that differentiated the groups in such a way that selection of patients could be improved to obtain improved outcomes.

This was a retrospective review where preprocedural, intraprocedural, and postprocedural parameters were left to the discretion of the investigator. The postprocedural stay was significant in duration and exhibited significant variability because patients frequently required hospitalization for wound care or for the treatment of other comorbidities.

Data for the overall technical success, limb salvage, and patency were frequently comparable with prior studies; however, some of the reports cited described better outcomes. One possible explanation is that a range of factors impact limb salvage, not just patency. In addition, the definitions for limb salvage and patency are not uniform across the various reports. For example, certain reports included patients treated for claudication in the statistics for limb salvage. In this report, limb salvage was evaluated only for patients who presented with CLI.

Furthermore, the study was not powered to evaluate the difference in outcomes between patients treated for single-level vs multilevel disease. Therefore, nonsignificant trends were noted that demonstrated improved outcomes for the treatment of multilevel compared with single-level disease with regards to primary patency and limb salvage. However, secondary patency was the only outcome evaluated that was found to be significantly different between the two patient cohorts.

CONCLUSIONS

The data in this study demonstrate that the technical success, limb salvage, and primary and secondary patency rates of the entire patient cohort are comparable with prior reports evaluating the endovascular treatment of infrapopliteal PAD and with historical surgical controls. In addition, patients who undergo a multilevel intervention involving the tibial vessels exhibit improved secondary patency compared with those who undergo intervention for lesions isolated to the tibial vessels. This may reflect increased distal disease burden for those patients who undergo isolated tibial intervention. Further study is required before formulating definitive recommendations for the endovascular treatment of infrapopliteal disease and before the use of adjunctive modalities to mitigate the potential for failure associated with endovascular therapy.

AUTHOR CONTRIBUTIONS

Conception and design: MS, SE, RL, MM, PF
Analysis and interpretation: MS, SE, IT, PF
Data collection: MS, SE, IT, RL, PF
Writing the article: MS, SE
Critical revision of the article: MS, SE, IT, RL, MM, PF
Final approval of the article: MS, SE, IT, RL, MM, PF
Statistical analysis: MS, SE, IT
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DISCUSSION

Dr Colleen Johnson (Springfield, Ill). I have two questions for you. Can you better define multilevel disease and whether that was a predominance of aortoiliac disease or femoropopliteal disease, as those behave a little differently postintervention. Secondly, in the manuscript you mention that your length of hospital stay was 6.2 days, plus or minus 9 days. Most of us would consider percutaneous interventions to be a 1?day procedure, and I am a little curious as to what the protocol or treatment paradigms were that surrounded those longer hospital stays.

Dr Mikel Sadek. In this study, the levels of vascular disease were divided into three categories: (1) the tibial or infrapopliteal vasculature, (2) the femoropopliteal vasculature, and (3) the aortoiliac vasculature. Single-level disease referred specifically to isolated disease of the infrapopliteal vasculature. Multilevel disease involved the infrapopliteal vasculature, as well as at least one additional level.

With regards to the length of hospital stay, patients were included in this study who were not in the hospital initially for treatment of their lower extremity peripheral arterial disease. Therefore, other medical issues frequently kept patients in the hospital beyond the typical postprocedural course for recovery.

Dr Anil Hingorani (Brooklyn, NY). I just wanted to ask about your patency rates in terms of how did you obtain patency rates? Did you just do duplexes of all the infrapopliteal arteries that you had ballooned?

Dr Sadek. Patency rates were obtained postprocedurally using a combination of ABI/PVR [ankle-brachial index/pulse volume recording] and duplex studies.

Dr Hingorani. So do you routinely get duplex studies of the infrapopliteal vessels on these types of patients?

Dr Sadek. Postprocedural follow?up was left to the discretion of the investigator. That said, the majority of investigators routinely obtain ABI/PVR and duplex studies postprocedurally.

Dr Victor Bernhard (Chicago, Ill). I am somewhat confused as to why the multilevel patients did better than the single?level patients, unless I missed your stratification of how much tibial disease was present in one group vs the other. Maybe you could clarify that.

Dr Sadek. The severity of tibial disease may be the reason why patients who underwent multilevel intervention exhibited improved outcomes as compared to patients who underwent single-level intervention. Additional analysis might clarify whether increased distal disease burden affected outcomes.

Dr Bernhard. In other words, you haven't stratified them according to the degree of tibial disease?

Dr Sadek. Correct.

Dr Hasan Dosluoglu (Buffalo, NY). The limb salvage was somewhat lower at 18 months, or 68%, if I got it correctly. Was limb salvage rate different between diabetics and nondiabetics in this series? Ironically the patients with one?level disease that you

thought that balloon angioplasty would be adequate, were the ones who did worse. So does that really mean that when you have a somewhat acceptable looking SFA [superficial femoral artery], little ragged and with diffuse disease, maybe, ironically, should be the ones that we should more aggressively consider bypasses, because that one?level correction of the most significant stenosis may not be enough. Maybe that is what your study is actually telling us. What do you think?

Dr Sadek. With regards to your first question and diabetes, we did not note a difference in limb salvage between diabetics and non-diabetics. And with regards to your second question, I think you make a valid point.

Dr Peter Schubart (San Jose, Calif). I wanted to commend you on your series and to note that you did have 10% more diabetic patients in the tibial vessel disease, which I think would tend to add to the trend of failure. I wondered whether, in looking at your patency data, whether in the multilevel disease you discriminated between failure in the proximal segment and failure in the tibials? In other words, was the tibial failure equivalent between the two groups?

Dr Sadek. For multilevel interventions, whenever there was a failure anywhere along the vascular tree that required reintervention, that affected the patency.

Dr Schubart. It might be interesting to analyze the data by infrapopliteal vs above the knee in terms of trying to see if you are treating apples and apples.

Dr Sadek. Absolutely. You make an excellent suggestion.

Dr Manju Kalra (Rochester, Minn). I too am intrigued by your results of multilevel vs single-level treatment. In patients with multilevel treatment, did you set out primarily to treat the femoropopliteal segment or the tibial segment? It would also be interesting to know the extent of disease and TASC [TransAtlantic InterSociety Consensus] classification of the femoropopliteal segments treated in order to assess their relative significance and contribution to clinical improvement following intervention.

Dr Sadek. With regards to multilevel disease, which came first, the chicken or the egg? This was a retrospective review of a prospectively maintained database; therefore, I cannot make a comment at this time regarding the intention for treatment. And with regards to TASC classification for the femoropopliteal lesions, that is an excellent suggestion for improving the manuscript.